

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INSTITUTE FOR AUTISM SCIENCE AND THE
INFORMED CONSENT ACTION NETWORK,

Plaintiffs,

-against-

CENTERS FOR DISEASE CONTROL
AND PREVENTION,

Defendant.

COMPLAINT

The above-captioned Plaintiffs, through their undersigned counsel, as for their Complaint against the above-captioned Defendant allege as follows:

INTRODUCTION

1. In 1986, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

2. By granting pharmaceutical companies immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of these often mandatory consumer products. Recognizing that it eliminated the financial

incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress placed the responsibility for vaccine safety in the hands of HHS and its agencies pursuant to 42 U.S.C. § 300aa-27(a) (“Mandate for safer childhood vaccines”) which provides, *inter alia*, that the Secretary of HHS “shall … make or assure improvements in, and otherwise use the authorities of the Secretary with respect to … research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”

3. The Plaintiffs and their affiliates are nonprofit groups involved in supporting families with autism spectrum disorder (“**autism**”), as well as supporting research into identifying the potential causes of autism in order to better understand how to treat and prevent autism (the “**Autism Groups**”).

4. In the past decade, no claim regarding vaccination has received more attention and publicity than the claim that vaccines cause autism. Likewise, federal health authorities claim to have studied the link between vaccines and autism more thoroughly than any other type of injury that parents claim are caused by vaccination. Federal health authorities assert that they carefully and methodically studied the issue and that the studies clearly and definitively support that vaccines do not cause autism.

5. Reflecting this conclusion, the Center for Disease Control and Prevention (“**CDC**”) unequivocally asserts on its website that “**Vaccines Do Not Cause Autism**”:



Various CDC department heads have also testified before Congress and declared on national news outlets that vaccines do not cause autism.

6. Despite these unequivocal assertions by the CDC, numerous peer-reviewed articles report that a majority of parents of children with autism have and continue to report one or more vaccines as a cause of their child's autism, including DTaP, Hepatitis B, Hib, PCV13, and IPV. Each of these vaccines are injected into babies three times during the first 6 months of life.

7. In order to provide assurance to parents of children with autism that their child's condition was not caused by one or more vaccines, the Autism Groups wanted to post the studies the CDC relied upon to assert that vaccines do not cause autism. Given the CDC's clear and unequivocal statements on this issue and its assertions that the science supporting this conclusion is robust, the Autism Groups expected to be able to identify numerous studies establishing that none of the vaccines, especially those given to babies, cause autism.

8. The Autism Groups, which include many doctors and scientists, engaged in research to identify these studies. However, as detailed below, the more research the Autism Groups conducted, the more apparent it appeared that these studies do not exist. Ultimately, the Autism Groups were unable to identify studies supporting the CDC's claim that vaccines do not cause autism with regard to any of the vaccines administered during the first six months of life pursuant to the CDC's childhood vaccine schedule.

9. The Autism Groups therefore submitted a request pursuant to the Freedom of Information Act ("FOIA") requesting the studies that CDC relies upon to claim that the DTaP vaccine, which is injected into babies at 2, 4, and 6 months of age, does not cause autism. The CDC failed to produce a single study to support that DTaP vaccines do not cause autism.

10. The Autism Groups also submitted a FOIA request to the CDC for the studies it relies upon to claim that the Hepatitis B vaccine (injected into babies at birth and then at 1 and 6 months of age), Hib vaccine (injected at 2, 4, and 6 months of age), PCV13 vaccine (injected at 2, 4 and 6 months of age), and IPV vaccine (injected at 2, 4 and 6 months of age) do not cause autism. The CDC also failed to provide a single study to support that any of these vaccines do not cause autism.

11. Given the CDC's broad and unequivocal assertions that "Vaccines Do Not Cause Autism" and that a robust body of science supports this conclusion, the Autism Groups seek copies of the studies which support this conclusion; or they want clear confirmation from the CDC that there are no studies which support that DTaP, Hepatitis B, Hib, PCV13, and IPV do not cause autism. If these studies do exist, they should be readily available to the CDC.

12. The Autism Groups sincerely hope that through this action the CDC will produce studies showing that DTaP, Hep B, Hib, PCV13, and IPV do not cause autism. However, given the history described below, they are concerned that the CDC probably has no such studies. If that is the case, the CDC should have to admit this fact and allow the public to weigh in on whether further proof is necessary before their government makes the unequivocal claim that "Vaccines Do Not Cause Autism."

13. The Autism Groups therefore bring this action seeking an order directing the CDC to provide a clear response to their FOIA requests in which the CDC must either admit it has no studies responsive to their requests or produce studies which are responsive to their requests.

PARTIES

14. Plaintiff, Institute for Autism Science, is a not-for-profit organization with an office located in Villa Park, California.

15. Plaintiff, Informed Consent Action Network, is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

16. There are other autism groups that have expressed strong support for the instant FOIA requests and action but did not participate due to concern that their corporate and health authority sponsors would terminate their funding.

17. Defendant, the Centers for Disease Control and Prevention (“CDC”), is an agency within the Executive Branch of the United States Government, organized within HHS. The CDC is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

BACKGROUND & FACTS

19. The CDC affirmatively asserts to the American public that “Vaccines Do Not Cause Autism” and has asserted this to the public for many years. The Autism Groups seek to obtain copies of the studies which support this claim; or alternatively, they are entitled to confirmation that there are no studies to support the claim for any of the vaccines injected into children during the first six months of life. If the studies do exist, which appears doubtful given what the Autism Groups have uncovered as detailed below, the Autism Groups would like to disseminate these studies to assure the members of their groups and the public that vaccines do not cause autism. If these studies do not exist, the Autism Groups are entitled to a clear “no responsive documents” response from the CDC.

I. National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34.)

20. Product liability attorneys provide a critical check in ensuring that unsafe products are improved or eliminated from the market through civil lawsuits. By the mid-1980s, pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products.¹ As the United States Supreme Court explained: “by the mid-1980’s … the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200.” *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011).

21. Instead of letting the usual market forces drive pharmaceutical companies to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), in 1986, which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccine products.²

22. Since 1983, the childhood vaccine schedule has gone from 7 injections of just 2 vaccines (DTP & MMR) to 50 injections of 12 vaccines (Hep B, DTaP, Hib, PCV13, IPV, IIV, MMR, VAR, Hep A, Men, Tdap & HPV).³ During that time, with a liability-free captive market of over 60 million children, vaccine sales in the U.S. have grown from just a few hundred million

¹ (Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994)) (By 1986 the “litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines,” and the remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market.)

² 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

³ <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.

dollars around 1986 to over \$35 billion in 2017.⁴ A copy of the CDC's childhood vaccine schedule from 1983 is attached as **Exhibit A** and a copy of the CDC's childhood vaccine schedule from 2019 is attached as **Exhibit B**.

23. By granting manufacturers immunity from actual or potential liability for injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of these products. Recognizing that it eliminated the incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress made the Secretary of HHS directly responsible for vaccine safety under the 1986 Act.

24. HHS' mandate to assure the safety of vaccines is codified at 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines" (the "**Mandate**") and provides:

- (a) **General rule.** In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall — (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
- (b) **Task force.** (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control. (2) The Director of the National Institutes of Health shall serve as chairman of the task force. (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the

⁴ <https://files.eric.ed.gov/fulltext/ED255480.pdf>; <https://www.bccresearch.com/market-research/pharmaceuticals/global-markets-for-vaccine-technologies-phm014g.html>

Secretary concerning implementation of the requirements of subsection (a).

(c) **Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

25. The requirements of the Mandate however, are only effective if HHS implements them. HHS has unfortunately failed to fulfill even its basic duties under the Mandate. The Task Force required by part “b” of the Mandate was disbanded in 1998, and HHS has not prepared or filed a single biennial vaccine safety report for Congress as required by part “c” of the Mandate. *Informed Consent Action Network v. United States Department of Health and Human Services*, 18-cv-03215-JMF, (Doc # 18) (S.D.N.Y, July 9, 2018). HHS has similarly failed to fulfill the far more difficult work required by part “a” of the Mandate to actually assure and improve vaccine safety. This failure is apparent from a recent letter exchange with HHS in which it was unable to support most of its vaccine safety claims with any data or studies.⁵

26. Nevertheless, there are other parts of the 1986 Act that HHS has vigorously fulfilled, specifically its obligations to (i) increase vaccine uptake and (ii) defend against legal claims that a vaccine caused an injury.

27. As for vaccine uptake, HHS spends over \$5 billion annually promoting and purchasing vaccines.⁶ It also maintains extensive programs working with manufacturers, state and local officials, and advocacy groups to assist in mandating vaccines, eliminating exemptions, and otherwise increasing vaccine uptake.

⁵ <https://www.icandecide.org/ican-vs-hhs-the-great-vaccine-debate/>

⁶ <https://www.hhs.gov/about/budget/index.html>

28. As for defending claims of vaccine injury in court, the 1986 Act established the Vaccine Injury Compensation Program (“**Vaccine Court**”), which is part of the U.S. Court of Federal Claims. Congress intended for the Vaccine Court to serve as a way to compensate people injured by vaccines.⁷ If an individual is injured by a vaccine, he or she must bring a claim in the Vaccine Court. HHS is the respondent in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury. 42 U.S.C. § 300aa-12 (“In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary [of HHS] shall be named as the respondent.”) Hence, HHS, while responsible for vaccine safety, is simultaneously responsible for the conflicting duty of defending against claims of vaccine injuries.

29. In the Vaccine Court, HHS is represented by the formidable resources of the U.S. Department of Justice (“**DOJ**”) and vigorously defends against any claim that a vaccine causes injury. *See, e.g.,* <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf> (“DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued aggressive defenses in compensation cases,” “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”)

30. Any studies or assertion by HHS or its agencies (including the CDC) which reflect that a vaccine that is already on the market causes a harm can and will be used against HHS in Vaccine Court to establish liability.

31. It is therefore critical that the safety of these vaccine products be established prior to licensure, but as the U.S. House Committee on Government Reform has found, the “overwhelming majority of members” of the CDC and FDA’s vaccine committees had conflicts of interest because of “substantial ties to the pharmaceutical industry,” and that these committees reflect “a system

⁷ <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>

where government officials make crucial decisions affecting American children without the advice and consent of the governed.”⁸

II. FOIA Request for Studies Supporting that DTaP Vaccine Does Not Cause Autism

32. The DTaP vaccine is intended to develop antibodies to certain antigens from the pertussis bacteria as well as certain toxins sometimes released by the diphtheria bacteria and tetanus bacteria.

33. Pursuant to the CDC’s childhood vaccine schedule, the DTaP vaccine is to be injected intramuscularly when a baby is 2-months, 4-months, 6-months, and 15-months of age. The two standalone DTaP vaccines currently licensed in the United States are Daptacel, manufactured and sold by Sanofi, and Infanrix, manufactured and sold by GSK.⁹ Neither vaccine was licensed based on a placebo controlled clinical trial.¹⁰ Moreover, the safety review period during these trials for these products was 28 days and six months, respectively.¹¹ Given the lack of a placebo control and the short safety review periods, these vaccines were never assessed prior to licensure for whether they could cause autism.

34. Since it was unknown prior to licensure whether these products can cause autism, there has been a long history of Congress and the scientific community requesting an answer to the question of whether the pertussis vaccines cause autism. However, as detailed below, the Autism Groups have learned that those requests have gone unanswered.

⁸ <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

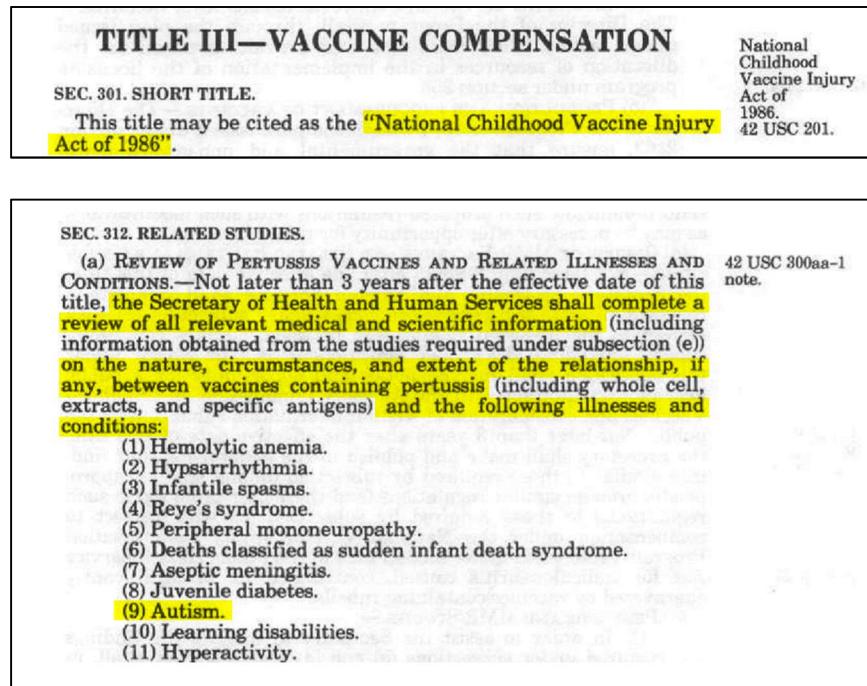
⁹ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

¹⁰ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

¹¹ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

a. **In 1986, Congress Directed HHS to Review Whether Pertussis Vaccines Cause Autism**

35. The concern that pertussis-containing vaccines could cause immune and brain dysfunction, including autism, was identified as a research priority in the 1986 Act.¹² Thus, Congress directed HHS to review the scientific evidence for whether pertussis-containing vaccines can cause, among other conditions, autism:¹³



36. In implementing the foregoing congressional directive, HHS commissioned the Institute of Medicine (“IOM”) in 1989 to identify any and all medical and scientific literature addressing whether pertussis-containing vaccines can cause autism.¹⁴ The IOM conducted this review and issued its report in 1991.¹⁵ In that report, the IOM explained that it could not find any

¹² <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

¹³ <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

¹⁴ <https://www.nap.edu/read/1815/chapter/1#v>

¹⁵ <https://www.nap.edu/read/1815/chapter/1>

evidence to support the claim that pertussis-containing vaccines do not cause autism.¹⁶ As explained by the IOM, this is because no studies “were identified that address the question of a relation between vaccination with DPT or its pertussis component and autism.”¹⁷

37. The following is a summary chart of the conclusions from the 1991 IOM report:

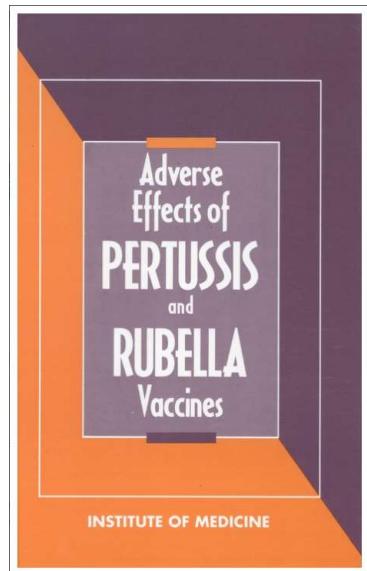


TABLE 1-2 Summary of Conclusions by Adverse Event for DPT^a and RA 27/3 MMR^b Vaccines

Conclusion	Adverse Events Reviewed	DPT Vaccine	RA 27/3 Rubella Vaccine
1. No evidence bearing on a causal relation ^c	Autism		
2. Evidence insufficient to indicate a causal relation ^d	Aseptic meningitis Chronic neurologic damage Erythema multiforme or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia	Radiculoneuritis and other neuropathies Thrombocytopenic purpura	
3. Evidence does not indicate a causal relation ^e	Infantile spasms Hypsarrhythmia Reye syndrome Sudden infant death syndrome		
4. Evidence is consistent with a causal relation ^f	Acute encephalopathy ^g Shock and “unusual shock-like state”	Chronic arthritis	
5. Evidence indicates a causal relation ^h	Anaphylaxis Protracted, inconsolable crying	Acute arthritis	

38. Due to this and other shortcomings identified in the IOM’s report, the IOM committee explained in its 1991 report:

In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. ... If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.¹⁸

b. In 2012, The IOM Again Reviewed Whether Pertussis Vaccines, including DTaP, Cause Autism

39. Nearly twenty years later in 2012, the CDC and its sister agency, the Health Resources and Services Administration (“HRSA”), commissioned the IOM to assess the evidence

¹⁶ <https://www.nap.edu/read/1815/chapter/2#7>

¹⁷ <https://www.nap.edu/read/1815/chapter/7?term=autism#152>

¹⁸ <https://www.nap.edu/read/1815/chapter/9>

bearing on whether pertussis-containing vaccines, including DTaP, cause autism, as this remained, according to the CDC and HRSA, one of the most commonly claimed injuries from this vaccine.¹⁹

40. The IOM convened a committee of experts to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines, which was composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law.²⁰

41. The CDC and HRSA presented a list of commonly claimed specific adverse events for the IOM to review, including asking the IOM to review whether there was any evidence, one way or another, regarding a potential causal relationship between DTaP vaccine and autism.²¹

42. Despite the intervening decades between the 1991 report and the 2012 report, the IOM's response to the CDC and HRSA remained unchanged. The IOM could not locate a single study supporting that DTaP does not cause autism. The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."²²

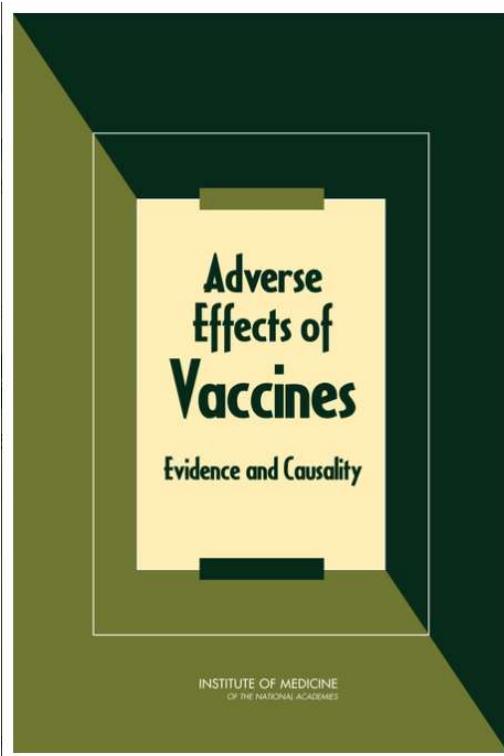
43. The following is the IOM's full explanation for this finding in its report:

¹⁹ <https://www.nap.edu/read/13164/chapter/2#2>

²⁰ <https://www.nap.edu/read/13164/chapter/1#v>

²¹ <https://www.nap.edu/read/13164/chapter/2#2>

²² <https://www.nap.edu/read/13164/chapter/12#545>



DT-, TT-, AND AP-CONTAINING VACCINES	545
AUTISM	
Epidemiologic Evidence	
<p>The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.</p>	
Weight of Epidemiologic Evidence	
<p><i>The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.</i></p>	
Mechanistic Evidence	
<p>The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.</p>	
Weight of Mechanistic Evidence	
<p><i>The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism as lacking.</i></p>	
Causality Conclusion	
<p>Conclusion 10.6: <i>The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.</i></p>	

44. The only study the IOM could locate regarding whether DTaP causes autism (Geier and Geier, 2004) concluded there *was* an association between DTaP and autism.²³

c. **In 2014, an HHS Agency Again Reviewed Whether Pertussis Vaccines, Including DTaP, Cause Autism**

45. Just a few years after the 2012 IOM report was released, the Agency for Healthcare Research and Quality (“AHRQ”) again conducted a review searching for any study bearing on a potential causal relationship between pertussis-containing vaccines, including DTaP, and autism.²⁴ HHS has explained that this report, published in 2014, represented “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”²⁵

²³ <https://www.nap.edu/read/13164/chapter/12?term=autism#545>

²⁴ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

²⁵ <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

46. As with the IOM reports from 1991 and 2012, the “comprehensive review” published by AHRQ in 2014 again concluded it could not identify a single study to support the claim that DTaP does not cause autism.²⁶

d. In 2017, the Director of the NIH, and the Chairman of the Interagency Autism Coordinating Committee Were Unable to Produce a Single Study to Support that DTaP Vaccine Does Not Cause Autism

47. On May 31, 2017, the White House convened a meeting at the National Institutes of Health (“NIH”) in which HHS’s published agenda for the meeting included “Causes of autism, including genetic and environmental influences.” In attendance at that meeting were approximately a dozen individuals from the government and outside groups, including:

- Dr. Francis Collins, Director (NIH)
- Dr. Joshua Gordon, Director, National Institute of Mental Health (NIMH) and, Chairman, Interagency Autism Coordinating Committee (IACC)
- Dr. Diana Bianchi, Director, Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD)
- Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences (NIEHS)
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
- Robert F. Kennedy Jr., Chairman, Children’s Health Defense
- Del Matthew Bigtree, President, Informed Consent Action Network

48. During this meeting, none of the directors from NIH could identify a single study which supported the claims that DTaP, nor any other vaccine given during the first six months of life, does not cause autism.

49. As a follow-up to this meeting, on June 21, 2017, Mr. Kennedy sent an email to Dr. Collins, Dr. Gordon, Dr. Bianchi, Dr. Birnbaum, and Dr. Fauci which included the following request:

As with most vaccines (other than MMR) there has not been a single study regarding whether DTaP causes autism. For example, the

²⁶ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

IOM in a 2011 report stated that the IOM could not confirm whether DTaP causes autism because no science had been done on that point. Nevertheless, the HHS baldly claims that all “Vaccines Do Not Cause Autism.” (<https://www.cdc.gov/vaccinesafety/concerns/autism.html>) Therefore, can you please explain how HHS claims that vaccines do not cause autism when it does not know whether DTaP causes autism?

In response to this email and numerous follow-up requests, the directors from the NIH failed to produce a single study to support that DTaP or any other vaccine given during the first six months of life does not cause autism.

e. **In 2017, Scientists from Major Universities in Canada, France and the United Kingdom Studying Aluminum Adjuvants Raise Serious Concerns that DTaP and Other Aluminum Adjuvanted Vaccines May be Causing Autism**

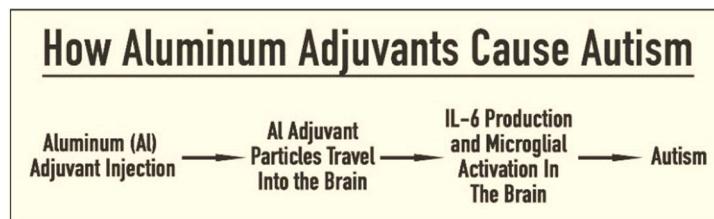
50. The DTaP vaccine contains tens of thousands of particles of aluminum hydroxide or aluminum phosphate. Aluminum hydroxide and aluminum phosphate are adjuvants used in inactivated vaccines to generate an immune response. The biological material in the DTaP vaccine bind to these aluminum adjuvant particles. Aluminum adjuvant particles cause cellular death in the area of the muscle tissue where it is injected, thereby triggering an immune response. Immune system cells that rush to that area will then carry the aluminum adjuvant particles to the lymph nodes, where antibody production occurs. Unlike biological material however, animal models reveal that the aluminum adjuvant pieces are then deposited in various bodily organs, including the brain. Aluminum adjuvant particles in the brain cause the release of, among other things, IL-6 in the brain, which is a known cause of neurological disorders including autism.

51. In June 2017, at least three scientists at major universities around the world with expertise regarding aluminum adjuvants raised a concern that aluminum adjuvants in vaccines could be contributing to neurological disorders, including autism. These letters each asserted that these scientists strongly supported the contention that aluminum adjuvants in vaccines may have

a role in the etiology of autism, and cited the peer reviewed literature supporting this contention. Copies of these three letters were provided to HHS, CDC and NIH, including a copy to Dr. Joshua Gordon, due to his position as Director of the National Institute of Mental Health (NIMH) and Chairman of the Interagency Autism Coordinating Committee. See Appendix C to **Exhibit C**.

52. Despite numerous attempts to facilitate a meeting with Dr. Gordon and these scientists, neither Dr. Gordon nor anyone else at HHS, CDC, or NIH agreed to meet with them to discuss their concerning conclusions regarding DTaP and other vaccines containing aluminum adjuvant.

53. Dr. Gordon and the other NIH directors and scientists were also provided a clear and detailed white paper which identified the peer-reviewed studies that support each step in the process for how aluminum adjuvants can cause autism. This science reflects that: injected aluminum adjuvant is taken up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the brain causes a release of interleukin IL-6 and microglial activation, leading to autism.²⁷ Depicted in simple terms:



This white paper has not been refuted by Dr. Gordon, any other directors at NIH, or by any scientists at CDC. A copy of this review is attached as **Exhibit G**.

²⁷ <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>

f. **On June 11, 2018, Dr. Stanley Plotkin Asked About Whether Studies Exist to Support that DTaP Vaccine Does Not Cause Autism**

54. The equivalent of the Nobel prize in vaccinology is called the “Plotkin Award.”

The medical textbook for vaccinology is called “Plotkin’s Vaccines.” The gavel used at the CDC’s Advisory Committee on Immunization Practices, which is the committee that decides the CDC’s childhood immunization schedule, is called the “Stanley A. Plotkin ACIP Gavel.” Dr. Plotkin has developed vaccinations for rubella, varicella, polio, rotavirus, rabies and cytomegalovirus. Dr. Plotkin is the Founding Father of the Pediatric Infectious Diseases Society. He has published over 800 peer-reviewed articles, most of which relate to vaccinology. Dr. Plotkin has received over 50 awards and honors for his work in vaccinology, including the French Legion of Honor Medal, and is a member of the IOM.

55. On June 11, 2018, Dr. Plotkin provided testimony under oath in a litigation that had received national media attention. The following is an excerpt from that testimony:

Q What was the IOM’s conclusion in 2011 about whether [the DTaP and Tdap] vaccines can cause autism?

A I’d have to look that up, but I feel confident they do not cause autism.

Q ... This is an excerpt from the IOM’s report [from 2011], right?

A Yes.

Q ... If you take a look at that section please, was the IOM able to identify a single study supporting that DTaP and Tdap do not cause autism?

A No, they did not identify a study.

Q ... If you don’t know whether DTaP or Tdap cause autism, shouldn’t you wait until you do know, until you have the science to support it to then say that vaccines do not cause autism?

A Do I wait? No, I do not wait because I have to take into account the health of the child.

Q And so for that reason, you’re okay with telling the parent that DTaP/Tdap does not cause autism even though the science isn’t there yet to support that claim?

A Absolutely.²⁸

²⁸ <https://www.youtube.com/watch?v=DFTsd042M3o>

56. There is arguably no scientist that has had a greater impact on vaccine policy at the CDC than Dr. Plotkin. A former member of the CDC's Advisory Committee on Immunization Practices, Dr. Paul Offit, explained that Dr. Plotkin "trained a generation of scientists" involved in vaccine policy and advocacy "to think like he thinks."

g. **On September 7, 2018, one of the World's Leading Experts on Autism and Mitochondrial Disorder and HHS's Autism Expert Attests Vaccines Can Cause Autism**

57. Dr. Andrew W. Zimmerman, M.D. is a world leading expert on autism, pediatric neurology and mitochondrial disorders, and has held numerous distinguished positions in this field, including as a professor at Johns Hopkins University School of Medicine, Harvard Medical School, and the University of Massachusetts Medical School and as the Director of Medical Research at the Kennedy Krieger Institute.²⁹

58. Dr. Zimmerman was the leading expert relied upon by HHS and DOJ in contesting claims that the MMR vaccine and thimerosal-containing vaccines cause autism in Vaccine Court, in what is known as the Autism Omnibus Proceeding ("AOP").

59. Initially, Dr. Zimmerman provided an expert report in the AOP on behalf of HHS claiming that MMR and thimerosal-containing vaccines do not cause autism. Shortly thereafter, Dr. Zimmerman explained to HHS and the DOJ that while he initially did not see any basis for how vaccines could cause autism, his opinion changed during the course of the AOP upon examining additional children, including those who had received DTaP vaccine, and concluded that vaccines had been a cause of their autism. HHS and the DOJ never alerted the other side about the change in Dr. Zimmerman's position, but rather continued to use Dr. Zimmerman's initial expert report despite the fact that he had informed them of the change in his opinion.

²⁹ <http://icandecide.org/documents/zimmerman.pdf>

60. Dr. Zimmerman has only recently revealed the foregoing in an affidavit, dated September 7, 2018, which provides, in relevant part:

1. I am a board certified, pediatric neurologist and former Director of Medical Research, Center for Autism and Related Disorders, Kennedy Krieger Institute, and Johns Hopkins University School of Medicine.
2. I was a Reviewer for the National Academy of Sciences 2004 report entitled IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM, which was prepared by the Immunization Safety Review Committee, at the request of the Centers for Disease Control and Prevention (CDC)...
4. In 2007, I was an expert witness for the Department of Health and Human Services in the Omnibus Autism Proceeding (O.A.P.) under the National Childhood Vaccine Injury Compensation Program.
5. With the assistance of the Department of Justice, I prepared and executed the attached expert witness opinion regarding Michelle Cedillo, on behalf of the Department of Health and Human Services ... [which] states in pertinent part as follows:

“There is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) Intoxication and autism. ...”
6. On Friday June 15th 2007 ... I spoke with DOJ attorneys... to clarify my written expert opinion.
7. I clarified that my written expert opinion regarding Michelle Cedillo was a case specific opinion as to Michelle Cedillo. My written expert opinion regarding Michelle Cedillo was not intended to be a blanket statement as to all children and all medical science.
8. *I explained that I was of the opinion that there were exceptions in which vaccinations could cause autism.*
9. More specifically, I explained that in a subset of children with an underlying mitochondrial dysfunction, vaccine induced fever and immune stimulation that exceeded metabolic energy reserves could, and in at least one of my patients, did cause regressive encephalopathy with features of autism spectrum disorder.

10. I explained that my opinion regarding exceptions in which vaccines could cause autism was based upon advances in science, medicine, and clinical research of one of my patients in particular.

...

12. Shortly after I clarified my opinions with the DOJ attorneys, I was contacted by one of the junior DOJ attorneys and informed that I would no longer be needed as an expert witness on behalf of H.H.S.

(emphasis added.)

61. A copy of Dr. Zimmerman's affidavit is attached as **Exhibit F**.

h. December 31, 2018, HHS Letter Exchange with ICAN

62. On October 12, 2017, Plaintiff Informed Consent Action Network sent a letter to HHS regarding vaccine safety subscribed to by over 55 organizations, whose members exceed 5 million Americans. A copy of this letter is attached as **Exhibit C**. This letter, in relevant part, provided:

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines³⁰

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.³¹ ...

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson³², recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.³³ Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we

³⁰ <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

³¹ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

³² Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC's vaccine safety claims. <https://www.ncbi.nlm.nih.gov/pubmed>

³³ <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

did. But we did. It's all there. It's all there. I have handwritten notes.”³⁴

...

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: “You can’t say that.”³⁵ When asked again, Dr. Healy explained: “The more you delve into it – if you look at the basic science – if you look at the research that’s been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*”³⁶

The CDC has also failed to address the science supporting a link between vaccines and autism.³⁷ For example, the CDC has not addressed ... a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.³⁸ There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.³⁹

63. HHS responded to the above in a letter dated January 18, 2018. A copy of this response is attached as **Exhibit D**. HHS’s response was required to be reviewed and approved by the following agencies within HHS: CDC, FDA, NIH, HRSA, and AHRQ. HHS’s response responded to the above question related to vaccines and autism as follows:

Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:

- <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>
- <http://nationalacademies.org/hmd/reports/2004/immunizationsafety-review-vaccines-and-autism.aspx>
- [http://www.jpeds.com/article/S0022-3476\(13\)00144-/pdf?ext=.pdf](http://www.jpeds.com/article/S0022-3476(13)00144-/pdf?ext=.pdf)

³⁴ <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

³⁵ <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>

³⁶ Ibid.

³⁷ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

³⁸ <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>

³⁹ <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

<http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at <https://iacc.hhs.gov/publications/strategic-plan/2017/>.

64. Upon examination of the links provided by HHS, it is clear that none of these links contain a single study which supports the claim that neither DTaP, nor any other vaccine given during the first six months of life, do not cause autism. As explained in ICAN's December 31, 2018 response (a copy of which is attached as **Exhibit E**):

HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

The *first* link is to a document entitled "Science Summary: CDC Studies on Thimerosal in Vaccines."⁴⁰ The studies in this document are plainly insufficient to support the claim that "vaccines do not cause autism" as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled "Immunization Safety Review: Vaccines and Autism."⁴¹ This report also cannot support the CDC's claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. ...

The *third* link is a study which only looks at one vaccine component – antigens – comparing 'vaccinated children' with 'vaccinated children' with different antigen exposure.⁴² This study again says nothing about whether any particular vaccine or HHS's childhood vaccine schedule causes autism. This study even concedes: "ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines.*"⁴³

⁴⁰ <https://www.cdc.gov/vaccinesafety/pdf/cdcestudiesonvaccinesandautism.pdf>

⁴¹ <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>

⁴² <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

⁴³ <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (emphasis added)

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.⁴⁴ ...

This study further ignores the fact that while “antigens” (as defined in the study) in vaccines have decreased since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased*. ...

But even putting all these limitations aside, this antigen study says nothing about whether any particular vaccine or group of vaccines cause autism, and, at best, relates to the potential connection between antigen exposure and autism (albeit in a study that, in its best light, is unreliable).

The *fourth* link HHS cites is the very IOM review from 2011 cited in our opening letter.⁴⁵ However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.⁴⁶ ...

The *fifth* (and final) link HHS cites in its letter is the “Strategic Plan for Autism Spectrum Disorder Research” by the Interagency Autism Coordinating Committee⁴⁷ Remarkably, this 196 page strategic plan outlines dozens of research priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.⁴⁸

The strategy plan even explains that “neuroinflammation” may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. ... The strategic plan also recognizes “immune dysregulation” – which again can be caused by vaccines – may cause autism.⁴⁹ ...

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that ... Dr. Zimmerman ... on November 9, 2016 ... answered “Yes” when asked under oath: “Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to

⁴⁴ <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

⁴⁵ <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

⁴⁶ <http://nationalacademies.org/HMD/Reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx>

⁴⁷ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

⁴⁸ https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

⁴⁹ <https://onlinelibrary.wiley.com/doi/book/10.1002/9781118663721>

a regressive autism?”⁵⁰ Dr. Zimmerman further testified that once HHS understands ... the causal relationship between vaccines and autism, “it will prevent the development of autism in quite a few children.”⁵¹

Dr. Zimmerman’s similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony...:

Lawyer: Do you agree with the statement that vaccines do not cause autism?

Dr. Kelley: No

Lawyer: Is it generally accepted in the medical community that vaccines do not cause autism?

Dr. Kelley: It is a common opinion.

Lawyer: It is generally accepted in the medical field that vaccines do not cause autism?

Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.

Lawyer: Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?

Dr. Kelley: Yes. They also say there is no proven association.

Lawyer: Do you agree with the position of the American Academy of Pediatrics?

Dr. Kelley: I agree with their position as a public health measure. I don’t agree with it scientifically.

Lawyer: You are actually arguing for a link between vaccines and autism in this case, aren’t you?

Dr. Kelley: I am.

Lawyer: And that is contrary to the medical literature, isn’t it?

Dr. Kelley: It’s not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.

Lawyer: Your opinion is contrary to, say, the opinion of the CDC, correct?

Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.⁵²

The view apparently held by HHS that “public health” demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. This view (i) ignores ... that the real “public health” emergency ... is that 1 in 36 children are now diagnosed with autism⁵³, (ii) stifles research into ... vaccines ... and autism, and (iii) forces HHS to ignore any science that does support a vaccine-autism connection.

⁵⁰ <https://books.google.com/books?isbn=1603588256>

⁵¹ <https://books.google.com/books?isbn=1603588256>

⁵² <https://books.google.com/books?isbn=1603588256>

⁵³ <https://www.cdc.gov/nchs/data/databriefs/db291.pdf>

On May 24, 2014, Dr. Thompson explained that the CDC is “paralyzed right now by anything related to autism . . .”⁵⁴ The reason . . . may be that . . . [i]f a single study conducted by HHS shows that even 1 in 5 cases of autism are caused . . . by vaccines, it would result in approximately \$1.3 trillion in liability⁵⁵ . . . and [a] decimation of HHS’s reputation . . .

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published.

HHS’s approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child’s autism.

i. **Autism Groups Submit FOIA Request to CDC regarding DTaP**

65. After two decades of demands upon CDC for proof that vaccines, including DTaP, do not cause autism, the CDC at this point must know what studies, if any, it has to support its assertion that vaccines, which would include DTaP, do not cause autism. Therefore, On June 21, 2019, the Autism Groups submitted a FOIA request to CDC seeking “All studies relied upon by CDC to claim that the DTaP vaccine does not cause autism.” (the “**DTaP-Autism FOIA request**”). The CDC has failed to produce a single study responsive to this request, nor has it asserted that it does not have any responsive studies.

66. It remains difficult for the Autism Groups to believe that the CDC does not have such studies, given that the CDC’s repeated assertion that vaccines do not cause autism -- an assertion which every health authority relies upon to provide medical advice and set policy with regard to research priorities related to autism.

⁵⁴ <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

⁵⁵ Since approximately 3.5 million American children have autism spectrum disorder and the approximate life time cost per individual is \$1.9 million, total cost of care for just 20% of these individual is \$1.3 trillion. www.autism-society.org/what-is/facts-and-statistics/

67. While it remains possible the CDC has studies that support that DTaP does not cause autism but has for some reason so far refused to produce such studies, it is far more likely that the CDC does not have those studies. Either way, the Autism Groups are entitled to know the truth.

III. FOIA Request for Studies Supporting that Hepatitis B Vaccines Do Not Cause Autism

68. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that neither Engerix-B nor Recombivax HB do not cause autism.” (the “**Hep B-Autism FOIA Request**”.)

69. The CDC’s childhood vaccine schedule provides that every infant receive a Hepatitis B vaccine on the first day of life and at one month and six months of life. The Hepatitis B vaccines licensed for use in babies are Engerix-B, manufactured by GSK, and Recombivax HB, manufactured by Merck.

70. Prior to licensure, neither of these Hepatitis B vaccines was evaluated for whether it could cause autism; nor did either of the clinical trials relied upon to license these vaccines contain a control group. Merck’s Recombivax HB was licensed after clinical trials that solicited adverse reactions for only five days after vaccination, and GSK’s Engerix-B was licensed after clinical trials that solicited adverse reactions for only four days after vaccination.⁵⁶

71. As described above, the AHRQ issued a report on vaccine safety in 2014 which HHS explained represents “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”⁵⁷ This “comprehensive review” apparently also searched for studies that would support the claim that the Hepatitis B

⁵⁶ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

⁵⁷ <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

vaccine does not cause autism, but did not identify for inclusion in the review a single study to support this claim.⁵⁸

72. To the contrary, it identified a study from the Stony Brook University Medical Center in New York, which found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth, compared to those who did not get this vaccine at birth.⁵⁹ The 2014 review summarizes the results of this study as follows:

Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.⁶⁰

Even though it found one study that showed an association and no studies to disprove this association, the AHRQ's review did not reach any conclusion regarding whether the Hepatitis B vaccine can cause autism.⁶¹ Rather, it concluded it does not know whether the Hepatitis B vaccine causes autism.⁶²

73. Nonetheless, given the CDC's assertion that "Vaccines Do Not Cause Autism" and that the CDC's childhood vaccine schedule provides that the Hepatitis B vaccine be injected three times by six months of age, the Autism Groups searched for studies conducted after 2014 to support the claim that Hepatitis B vaccine does not cause autism. The Autism Groups were unable to identify any such studies. The CDC has also not produced any studies responsive to the Hep B-Autism FOIA Request nor confirmed that it does not have any responsive studies.

⁵⁸ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

⁵⁹ http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf

⁶⁰ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

⁶¹ https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

⁶² https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

IV. FOIA Request for Studies Supporting that Prevnar 13 Does Not Cause Autism

74. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that Prevnar 13 does not cause autism.” (the “**“Prevnar-Autism FOIA Request”**.”)

75. Prevnar 13 is manufactured by Pfizer and the CDC’s childhood vaccine schedule provides that every baby receive Prevnar 13, a vaccine for pneumococcal, at two months, four months and six months of life.

76. Prior to licensure, Prevnar 13 was not assessed for whether it can cause autism. Instead, Prevnar 13 was licensed in 2010 based on a clinical trial in which Pfizer used Prevnar (an earlier version of the vaccine) as the control.⁶³ In turn, Prevnar was licensed based on a clinical trial in which the control was “an investigational meningococcal group C conjugate vaccine [MnCC].”⁶⁴ MnCC, is an unlicensed product and hence was obviously never licensed based on a placebo-controlled trial.⁶⁵

77. The clinical trial for Prevnar 13 found that “Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients.”⁶⁶ The FDA defines a “serious adverse event” is follows:

An adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor [meaning, the pharmaceutical company seeking licensure or the investigator hired by that pharmaceutical company], it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the

⁶³ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>; <http://labeling.pfizer.com/showlabeling.aspx?id=134>

⁶⁴ <http://labeling.pfizer.com/showlabeling.aspx?id=134>

⁶⁵ See tables above.

⁶⁶ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

ability to conduct normal life functions, or a congenital anomaly/birth defect.

Despite the serious adverse reaction rate seen in children receiving Prevnar 13 and those receiving Prevnar, licensure for Prevnar 13 to be injected into babies was still granted because it had a similar serious adverse reaction rate as the control group did when receiving Prevnar.⁶⁷

78. The Autism Groups are also not aware of a study after licensure to support that Prevnar 13 does not cause autism. On the other hand, there are many parents who have reported that their children began exhibiting the behavioral features of autism shortly after receiving this vaccine. Therefore, these concerns are very real concerns for the members of the Autism Groups, which is why the groups are so interested in posting the studies if they exist, or advocating for additional research if the studies do not exist. For example, a set of triplets all received Prevnar on the same day. Within twenty-four hours, all three of them suffered rapid declines in their behavioral and cognitive functions. An abridged three minute version of the interview with the parents of these triplets is available at <https://www.youtube.com/watch?v=KN0qxO3G7eo> and the following is a transcription of portion of this three minute video:

Mother of the Triplets: We have triplets. Two boys and a girl: Richie, Robbie, and Claire. ... Every single day they were smiling and laughing and looking at each other and engaging in each other. On June 25th, 2007, we brought them in for the pneumococcal shot [Prevnar]. My daughter still has the mark on her leg from the shot. She was the first one to get it and she screamed and never really stopped screaming after that, but we continued, we didn't know. We did the boys, as well.

By noon, Claire shut completely off. It was as if she was blind and deaf, and all she did at that moment was stare at the ceiling. So that was at noon. We had the shot at 10 a.m.

At two o'clock, we watched Ritchie shut off. They lost all their reflexes. I'm an educational audiologist. I actually did the test for

⁶⁷ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

the stapedial reflex, which is a little muscle in the middle ear, just to see if a muscle they can't control was still working, and it didn't. The stapedial reflex dampens sounds, so your ears don't hurt from a really loud sound. And both of them had no stapedial reflex. They stopped blinking, stopped yawning, stopped coughing, stopped sneezing.

The worst was when we saw the final one shut down. Robbie, from that moment on, had a stunned look on his face. If you asked, or said his name, he still acted deaf, or acted like he couldn't hear. Although they did have normal hearing. I had it all tested. But he lost his happiness.

Three months after the shot, they were no longer engaged in anything or anyone. We were told it was genetic. And then we were told by geneticists that there is no possible way three children would shut off on the same day.

We had severe autism spectrum disorder for all three kids entering kindergarten. We have spent hundreds of thousands of dollars trying to recover them. The only person we got back was Robbie. The one that was last to shut off. Ritchie can only say single, maybe two, words together. Claire is still completely nonverbal, not potty trained. And Robbie is approaching grade level, but severe OCD.

Father of the Triplets: So, you've got, say a six-or seven-year-old child, who is not potty trained. And at two or three, four o'clock in the morning they fill their diaper. Well you can assume that pretty uncomfortable, so they take it off. Pretty soon it's all of them, it's all over the bed. In short order, it's all over me, it's all over her. I'm snapping at her, she's snapping at me. We are both snapping at the kid who is the only innocent party in the whole scenario. And the one thing that is conspicuously absent from that scenario is anybody who told you that shot was safe. They are all asleep in their bed. They haven't got a problem in the world.

79. Given the CDC's assertion that "Vaccines Do Not Cause Autism" and that the CDC's childhood vaccine schedule provides that Prevnar 13 be injected three times by six months of age, the Autism Groups searched for studies which support that Prevnar 13 does not cause autism. The Autism Groups could not identify any such study. The CDC has also not produced

any studies responsive to the Prevnar-Autism FOIA Request, nor has it asserted it does not have any responsive studies.

V. FOIA Request for Studies Supporting that Hib Vaccine Does Not Cause Autism

80. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that Hib vaccines does not cause autism.” (the “**Hib-Autism FOIA Request**”.)

81. There are three Hib vaccines used in the United States -- ActHIB (manufactured by Sanofi), Hiberix (manufactured by GSK), and PedvaxHIB (manufactured by Merck) – and the CDC’s childhood vaccine schedule provides that every baby receive a Hib vaccine at two months, four months and six months of life.

82. Like Hep B and Prevnar 13, none of these Hib vaccines were assessed, prior to licensure, for whether they can cause autism. Likewise, none of the clinical trials relied upon to license these vaccines included a placebo control group or had a safety review duration longer than thirty-one days after injection.

83. Nevertheless, given the CDC’s assertions that “Vaccines Do Not Cause Autism” and that the CDC’s childhood vaccine schedule provides the Hib vaccine be injected intramuscularly three times by six months of age, the Autism Groups searched for studies which support that Hib vaccines do not cause autism. The Autism Groups were unable to identify any such study. The CDC has also not produced any such studies in response to the Hib-Autism FOIA Request, nor has it asserted that it does not have any responsive studies.

VI. FOIA Request for Studies Supporting that IPV Vaccine Does Not Cause Autism

84. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that inactivated polio vaccine (‘IPV’) does not cause autism.” (the “**IPV-Autism FOIA Request**”.)

85. The only vaccine currently used in the United States for polio is the inactivated polio vaccine (“IPV”), tradename Ipol, licensed in 1990, and manufactured by Sanofi. The oral polio vaccine (“OPV”) was used in the United States until 2000 when it was discontinued and replaced with the IPV because the OPV was found to cause paralysis.

86. Like the previously listed vaccines, prior to licensure, IPV was never assessed for whether it can cause autism. The clinical trial relied upon to license IPV had no control group and a safety review period of three days.

87. Given the CDC’s assertion that “Vaccines Do Not Cause Autism” and that the CDC’s childhood vaccine schedule provides that IPV be injected intramuscularly three times by six months of age, the Autism Groups searched for studies to support that IPV does not cause autism. The Autism Groups were unable to find any such study. The CDC has also not produced any studies responsive to the IPV-Autism FOIA Request, nor has it asserted that it does not have any responsive studies.

VII. Cumulative Exposure to Vaccines Given During the First Six Months of Life and Autism

88. On July 25, 2019, the Autism Groups submitted a FOIA request to CDC requesting “Copies of the studies the CDC relies upon to claim that the cumulative exposure of vaccines it recommends that babies be administered during the first six months of life do not cause autism.”

89. Given the CDC’s assertion that “Vaccines Do Not Cause Autism,” the Autism Groups searched for studies to support that the cumulative exposure to all vaccines given during

the first six months of life do not cause autism. The Autism Groups were unable to find any such studies. The CDC has also not produced any studies responsive to this request, nor has it asserted that it does not have any responsive studies.

VIII. The Truth Matters

90. The CDC is seen as one of the most trusted authorities in the world with regard to vaccinations. Its pronouncements regarding vaccines impact policy, research, and funding priorities across all HHS agencies as well as research institutions in the United States and around the world. The CDC should be able to support, with credible robust studies, the claims it makes regarding vaccine safety -- especially for the vaccine safety issue it has claimed to have studied more thoroughly than any other claimed vaccine injury.

91. The most recent data from CDC reveals that 1 in 36 children born this year in the United States will have an autism diagnosis. This is a true epidemic. The CDC and health authorities have conducted a decades-long media campaign seeking to assure parents that vaccines do not cause autism. But, making such statements without supporting studies is irresponsible. Perhaps this is why a majority of parents of children with autism still assert, based on their lived experience, that it was one or more vaccines that caused their child's autism. If the CDC and health authorities had spent resources on conducting the proper studies, rather than media relations, maybe they could produce the studies today which actually support this claim.

92. Administrative appeals were filed in regard to each of the FOIA requests discussed above; however, the statutory time to respond to same has elapsed. As such, all administrative remedies have been exhausted.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

- a. Provide for expeditious proceedings in this action;

- b. Enter an Order directing the CDC to (i) assert it does not have studies to support that DTaP vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that DTaP vaccines do not cause autism;
- c. Enter an Order directing the CDC to (i) assert it does not have studies to support that Hepatitis B vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that Hepatitis B vaccines do not cause autism;
- d. Enter an Order directing the CDC to (i) assert it does not have studies to support that Prevnar 13 does not cause autism or (ii) forthwith provide copies of the studies which support that Prevnar 13 does not cause autism;
- e. Enter an Order directing the CDC to (i) assert it does not have studies to support that Hib vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that Hib vaccines do not cause autism;
- f. Enter an Order directing the CDC to (i) assert it does not have studies to support that IPV does not cause autism or (ii) forthwith provide copies of the studies which support that IPV does not cause autism;
- g. Enter an Order directing the CDC to (i) assert it does not have studies to support that the cumulative exposure to the vaccines it recommends babies receive during the first six months of life does not cause autism or (ii) forthwith provide copies of the studies which support that the cumulative exposure to the vaccines it recommends babies receive during the first six months of life does not cause autism;

- h. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and
- i. Grant such other and further relief as the Court may deem just and proper.

December 31, 2019

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